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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,016

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Michel Gilbert

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11/08/2006

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,016

Applicant(s)

GILBERT ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 35-50 are pending.

Objections/Rejections Withdrawn

1. **Drawings** The Brief Description of the Drawings is now complete in light of the fact that Figure 3 shows two amino acid sequences which are identified by sequence identifiers (SEQ ID NO).

2. **Claim Objections Withdrawn** Claim 40 objected to because of the following informalities
has been obviated by amending the claim to define the meaning of the term “FLAG” with a SEQ ID NO. the recitation of abbreviations in the claims is permitted upon their definition at their first appearance in the claims. The meaning of these terms should be set forth at their first appearance in the claims. Appropriate correction is required.

3. **Claim Objections Withdrawn** Claim 48 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend for other claims in the alternative and not multiple claims simultaneously has been obviated through amending claims 48 to no longer depend from both claim 41 and 37 simultaneously.

Response to Arguments/ Objections/Rejections Maintained

1. Applicant's arguments filed May 4, 2006 and August 18, 2006 have been fully considered but they are not persuasive.

2. **Specification** The disclosure objected to because it contains an embedded hyperlink and/or other form of browser-executable code has been partially obviated, but the web address www.ncbi.nlm.nih.gov is still internet browser-executable code and the www. Must be removed.

Removal of the hyperlink at page 9, line 22 is required, as well as any other hyperlinks in the instant Specification.

4. **Double Patenting** Claims 35-47 and 49-50 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6709834, is herein maintained in light of an effective terminal disclaimer not having been submitted.

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1. ***Rejection Maintained Claim Rejections - 35 U.S.C. § 112*** : The rejection of claims 35-50 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID Nos: 1-2 and therefore the written description is not commensurate in scope with the claims drawn to an isolated polypeptide molecule that only shares 90% identity with an amino acid sequence set forth as SEQ ID NOs: 2. The specification does not provide written descriptive support for the claimed invention of “at least 90%” identical to an amino acid sequence as set forth in SEQ ID NO 2 . Within the scope of the claimed invention of at least 90% identical to an amino acid sequence of SEQ ID NO 2 are sequences that are homologs, or allelic variants of SEQ ID No 1 and 2 is traversed on the grounds that :

Applicant has provided the amino acid sequence of the claimed genus of polypeptides, defined it's biological activity and describe a functional assay to determine the activity of the polypeptides when changes are made.

2. It is the position of the examiner that traversal directed to enablement does not show possession of the genus of polypeptides at the time of filing the instant Specification. The instant Specification does not describe the critical region of amino acids that is required for the sialyltransferase activity, and the claims encompass changes at any location.

a. The truncated polypeptide of amino acids 1-328 has activity, but no polypeptides that are smaller than 1-328 amino acids have been described to evidence the claimed biological activity and meet the recitation of 90% or 95% identity much

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smaller sub fragments of the recited ranges of amino acids defined by the phrase “an amino acid sequence with”.

b. Additionally, all of the claims still recite the phrase “comprises an amino acid sequence with at least 90% identity to residues 1-328” or “to residues 1-430”, and therefore claim a genus of polypeptides with the recited functional activity that share an amino acid sequence with SEQ ID NO 2.

While it is true that all of the claims have been amended to recite the phrase “**over the entire length of residues 1-328**” or “residues 1-430”, this phrase is unclear as the residues do not refer to SEQ ID NO 2, but may refer to a sequence that is 90% identical, the sequence of which is not clearly nor distinctly claimed as where the changes have been made have not been defined in the Specification nor claimed, or it may refer to a molecule that is larger than 1-328 of SEQ ID NO 2 and results in a molecule that is 90% identical, but what this sequence is, is not clear. The claims as amended are unclear as to what sequence or range of amino acids the newly amended claim limitations refer, and the claim still recites the phrase “an amino acid sequence of 90% identity to amino acids 1-328 of SEQ ID NO 2, so could refer to the amino acid sequence that shares identity could be from any location within the recited range of amino acids. The rejection of record is herein maintained, in light of the lack of clarity with respect to what the newly submitted phrase refers. This rejection could be obviated by amending the claims to recite -----wherein the α -2,3 sialyltransferase polypeptide comprises the amino acid sequence of residues SEQ ID NO 1-328 of SEQ ID NO 2 or an amino acid sequence that shares at least 95% identity with amino acid residues 1-328 of SEQ ID NO 2----- ; this claim amendment would claim the invention commensurate in scope with Applicant’s traversal.

Art Unit: 1645

1. ***Rejection Maintained Claim Rejections - 35 U.S.C. § 102*** The rejection of Claims 35-39 under 35 U.S.C. 102(b) as being anticipated by Gilbert et al (1996, Journal of Biological Chemistry, Reference of Record, Applicant's IDS submission) is traversed on the grounds that the newly submitted combination of claim limitations are not disclosed by Gilbert et al.
2. It is the position of the examiner that the combination of claim limitations newly submitted are unclear as to which amino acids the newly submitted phrase refers (see discussion of new limitations above under 35 USC 112, above, incorporated herein by reference). This rejection could be obviated by amending the claims to recite the combination of claim limitations suggested by the examiner above, and to be commensurate in scope with Applicant's traversal.
3. **Rejection Maintained :** The rejection of claims 41-47 under 35 U.S.C. 102(e) as being anticipated by Paulson et al (US Pat. 6,399,336; effective filing date January 16, 1997; reference of record; Applicant's IDS submission)) is traversed on the grounds that the newly submitted combination of claim limitations are not disclosed by Paulson et al.
4. It is the position of the examiner that the combination of claim limitations newly submitted are unclear as to which amino acids the newly submitted phrase refers (see discussion of new limitations above under 35 USC 112, above, incorporated herein by reference). This rejection could be obviated by amending the claims to recite the combination of claim limitations suggested by the examiner above, and to be commensurate in scope with Applicant's traversal.

New Claim Limitations/New Grounds of Rejection

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 35-40 are rejected on the ground of a provisional nonstatutory obviousness-type double patenting as being unpatentable over claim 43-46 of U.S. Application 10/821,573

Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instantly claimed invention claims a genus of polypeptides with α -2,3

sialyltransferase activity that share “an amino acid sequence with at least 90% identity to

residues 1-328 of SEQ ID NO 2”, SEQ ID NO 2 originating from *Campylobacter jejuni*, and the

two primers used to define the claimed polypeptide with α -2,3 sialyltransferase activity of

copending Application 10/821,573 is a species of α -2,3 sialyltransferase polypeptide obtained

from *Campylobacter*, an obvious species within the instantly claimed genus.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 35-50 recites the limitation "over the entire length" in reference to a α -2,3 sialyltransferase polypeptide, the size of which may be larger or smaller than residues 1-328 of SEQ ID NO 2, as the claim encompasses polypeptides that share 90% and 95% identity to residues 1-328 of SEQ ID NO 2. It is not clear to what residues the newly submitted range refers with respect to molecules that are larger than 1-328 of SEQ ID NO 2, and it is also not clear what the range refers to with respect to molecules that are smaller than residues 1-328 of SEQ ID NO 2, as the newly submitted range of residues is not defined by a SEQ ID NO, and the claims still encompass molecules that comprise fragments of the recited range of amino acids 1-328 and 1-430 that share at least 90% and 95% identity with SEQ ID NO 2 of the claimed ranges. There is insufficient antecedent basis for this limitation in the claim with respect to any residues that share fewer or greater than the claimed range of residues, and to molecules that comprise an amino acid sequence of SEQ ID No 2 with the claimed % identity to the reference range of amino acids. This rejection could be obviated by amending the claims to recite the suggested combination of claim limitations set forth above under Response to Arguments under 35 USC 112.

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Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
November 1, 2006



MARK NAVARRO
PRIMARY EXAMINER